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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,309	07/02/2001	Robert B. Odell	P-3946C1C1	1739

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EXAMINER	
HUYNH, LOUIS K	
ART UNIT	PAPER NUMBER
3721	17

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,309	ODELL ET AL.	
	Examiner	Art Unit	
	Louis K. Huynh	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-29 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29 and 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 19-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

Lawecki discloses a method for producing glass syringe barrels (column 3, lines 35-43) including a step of transferring the glass syringe barrels to an enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the syringe barrels from the time the syringe barrels are fabricated to the time the syringes barrels are placed in sealed containers for shipment (abstract). The method of Lawecki meets all of applicant claimed subject matter except for the detailed process of forming a glass syringe.

However, Logothetis discloses a method for forming a glass syringe barrel (1) on a forming device (column 3, lines 40-43) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (column 3, lines 57-62; Figures 1 & 2); the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (column 5, lines 8-14; Figure 5); the syringe barrel is then heated to an annealing temperature (column 4, lines 24-27).

Therefore, it would have been obvious to an ordinary skilled in the art at the time the invention was made to have modified the method of Lawecki by having provided a forming

device for forming the glass syringe barrels, as taught by Logothetis, in order to produce glass syringe barrels prior to transferring the glass syringe barrels the enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the glass syringe barrels during the processing of the glass syringe barrels.

With respect to claim 20, the modified method of Lawecki further includes the steps of: applying a tip cap, applying a stopper, etc. to the glass syringe barrel (column 8, lines 19-29) to form a glass syringe assembly; placing the glass syringe assembly in a holder (68) to form an array of eight glass syringe assemblies (column 7, lines 17-21), enclosing the array in a second container (128) (column 7, lines 25-28).

With respect to claim 21, the modified method of Lawecki would include the steps of: supplying a cylindrical glass tube (2) to the forming device; heating the upper end of the glass tube (2) to a pliable state for forming a flange (column 3, lines 57-62; Figures 1 & 2); heating the lower end of the glass tube to a pliable state for shaping the lower end to receive a cannula needle (3) (column 5, lines 8-14; Figure 5).

With respect to claim 22 and 23, since the temperature range for heating glass to a pliable state for shape forming and the annealing temperature range are known by those skilled in the art (applicants' specification page 19, lines 19-27); therefore, the temperature range for heating the glass tube is considered to be about 760°C to 1100°C, and the temperature range for heating the glass tube to an annealing temperature is considered to be about 560°C.

With respect to claims 24 and 25, the modified method of Lawecki would include the step of cleaning the glass syringe by directing a stream of filtered, ionized air toward the glass

syringe to keep contaminants from setting on the glass syringe (column 4, lines 22-24) and to reduce static charge of the glass syringe barrels (column 7, lines 6-10).

With respect to claims 26 and 27, Lawecki discloses a HEPA filter (50) including an independent blower (column 4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment. Lawecki further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (column 4, lines 51-54).

With respect to claims 28 and 29, the modified method of Lawecki would include the steps of: transferring the glass syringe barrels to an intermediate isolation module for lubricating the inner surfaces of the syringe barrels (column 8, lines 19-25); and transferring the glass syringe barrels to the packaging isolation module (14).

3. Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of AAPA (Applicant Admitted Prior Art).

With respect to claims 33, 34, 37 and 38, Lawecki discloses a method of producing plastic syringe barrels including the steps of: forming a plastic syringe barrel (126) in a forming device (18); transferring the plastic syringe barrel to an enclosure (10) of class 100 environment (column 3, lines 5-18); directing a stream of filtered air to clean the plastic syringe barrel (column 4, lines 22-24); forming a tip cap (column 8, lines 1-7); delivering the tip cap to the enclosure (10); directing a stream of filtered air to clean the tips cap (column 8, lines 7-10); and assembling the tip cap to the plastic syringe barrel (column 8, lines 10-18); filling the plastic

syringe barrel; inserting a stopper (inherent) to the plastic syringe barrel to form a prefilled syringe barrel (column 2, lines 35-38). The method of Lawecki meets all of applicant's claimed subject matter but lacks the specific teaching of the way the plastic syringe being filled.

However, with regard to the filling of the syringe barrel, AAPA discloses that the syringe barrel can be filled by known method (page 31, line 19 – page 32, line 6). For example, the U.S. 5,620,425 to Heffernan et al. teaches a method for filling a syringe barrel through the open tip end, the U.S. 5,597,530 to Smith et al. teaches a method for filling a syringe barrel through the open bottom end.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified filled the plastic syringe barrel using a suitable method of either through the proximal end or through the distal end of the plastic syringe barrel, as taught by AAPA, in order to form a prefilled syringe barrel.

With respect to claims 34 and 38, the modified method of Lawecki would include a step of packaging the prefilled syringe barrels.

With respect to claims 35, 36, 39 and 40, AAPA through the references to Heffernan et al. (US 5,620,425) and to Smith et al. (US 5,5,97,530) teaches that the prefilled syringe barrels are sterilized before they are labeled and packaged for use (Heffernan, column 7, lines 11-14; Smith, column 6, lines 26-44). Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified the method of Lawecki by having included the step of sterilizing the prefilled syringe barrels prior to the step of packaging, as taught by AAPA, in order to produce sterilized prefilled syringe barrel packages ready for use.

Response to Arguments

4. Applicant's arguments filed October 22, 2003 (Paper No. 16) with respect to claim 19 have been fully considered but they are not persuasive. Applicant contends that the teaching of Lawecki calls for forming a clean syringe barrel and continuously maintain the barrel's cleanliness thereafter; there is no suggestions in Lawecki to have a syringe barrel be formed outside of a clean environment and then introduced thereinto; consequently, there is no motivation or suggestion to modify Lawecki to introduce syringe barrels formed in accordance with Logothetis outside of a clean environment and then introducing the syringe barrels into a clean environment. This is not found persuasive because the claim language neither requires that the syringe barrels be formed outside of a clean environment nor precludes the syringe barrels be formed inside a clean environment. The Lawecki reference discloses in FIG. 1 and FIG 2 a forming apparatus 18 including forming platens 22 and 24 which occupies a terminal end of the enclosure 12 and is respectively connected to a fixed wall 36 and a movable wall 28 (via hinge 26) of the enclosure (column 3, lines 49-66). As such, the syringe barrels are considered to be formed outside of the enclosure 12 and are transferred (by a robot) to the enclosure 12 after they are formed (column 4, lines 1-9). The Lawecki reference does not limit to any one particular process and/or apparatus for forming the syringe barrels, glass syringe barrels is one of a preferred embodiment (column 3, lines 35-48). Thus, the method of Lawecki meets all of applicant's claimed subject matter except for the specific steps of forming the glass syringe barrels. The Logothetis reference discloses a method of forming glass syringe barrels which fills the deficiency of the Lawecki reference. Hence, a prima facie of obviousness has been reasonably set forth (*See* Office Action at pages 2-3).

5. Applicant's arguments filed October 22, 2003 (Paper No. 16) with respect to claims 33 and 37 have been fully considered but they are not persuasive. Applicant contends that there is no disclosure or suggestion in Lawecki to provide tip caps and to air clean the tip caps which are delivered into the clean environment. This is not found persuasive because the reference to Lawecki teaches that additional manufacturing modules may be added to allow more than one molded article to be manufactured and the molded articles are assembled by in the packaging module (column 8, lines 1-18). Tip cap and/or stoppers are such additional molded articles to be assembled with the syringe barrels for enabling filling of the syringe barrels with a fluid as preferred in another alternative (column 8, lines 19-29). As discussed above and illustrated in Figs. 7, additional forming apparatus with similar feature to the syringe barrel forming apparatus, occupies a terminal end of an additional module and the additional articles are air cleaned and transferred to the additional module after they are formed. Thus, the method of Lawecki meets all of applicant's claimed subject matter except for the way the syringe barrels being filled. The AAPA discloses through Heffernan and Smith the processes of filling the syringe barrels which fills the deficiency of the Lawecki reference. Hence, a prima facie of obviousness has been reasonably set forth (*See* Office Action at pages 4-5)

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LH
November 18, 2003

JOHN SIPOS
PRIMARY EXAMINER